

10/627,502

## REMARKS

This application is rejected under 35 U.S.C. § 112, first paragraph, for the reasons noted in the official action. The inadequate written description rejection is acknowledged and respectfully traversed in view of the following remarks.

The Examiner states that the specification fails to teach the recited features of claims 6-11. The pending claims are revised and are now believed to recite a cannula as disclosed by the pending specification. Accordingly, the Applicant respectfully requests withdrawal of the raised rejections under 35 U.S.C. § 112, first paragraph, at this time in view of the above remarks and the entered claims amendments.

Claims 6-11 are then rejected, under 35 U.S.C. § 103, as being unpatentable over Derrick `491 in view of Caldwell `800. The Applicant acknowledges and respectfully traverses the raised obviousness rejection in view of the following remarks.

Derrick `491 concerns an apparatus and method for respired gas collection and analysis. The apparatus includes a cannula body member 88 separated into two nasal cannulas 92 and 94 by a solid central portion 90. Nasal cannula 92 has inhalation gas ports 96 at a portion of the body member 88 to deliver oxygen, a region between the patient's mouth and nose. Additionally, each of the two nasal cannulas 92 and 94 has a base member 100 and 102, respectively, connected to the body member 88 at their lower portions. Each of the two nasal cannulas 92 and 94 has a slidably mounted upper tubular member 104 and 106, respectively, to provide a slidable telescopic mounting. Each of the nasal cannulas 92 and 94 has one or more gas ports 108 and 110 located proximate the ends of the upper tubular members 104 and 106 to maximize or optimize gas flow through the cannulas 92 and 94. This construction enables adjusting a length of each of the nasal cannulas 92 and 94 to meet the particular needs of a particular patient.

The cannulas as specifically taught and disclosed by Derrick `491 are constructed with multiple individual pieces. Each cannula has the main body and a base member which may or may not be integral with each other. An individual slidable tubular member slidably communicates with the base member so as to provide adjustability to the length of the nasal cannulas or nares. This is arrangement contrary to the claims of the present application which

specifically recite first and second fixed length hollow nasal prongs. That is, the nasal prongs are formed integrally with the hollow body and have a non-adjustable fixed length. As a result of this, the length of the nasal prongs can not be adjusted as specifically taught and disclosed by Derrick `491.

As shown in Fig. 4 of Derrick `491, a portion of the cannula body member 88 located below the base of the cannula 92 contains one or more inhalation gas ports 96 for delivery of oxygen and some other inhalant gas(es) to the region between the patient's nose and mouth. The present invention, on the other hand, is directed at supplying all of the treating gas through the cannula from the treating gas entrance to the treating gas exit without allowing any of the treating gas to exhaust or exit through a side wall of the inhalation manifold. Accordingly, it is respectfully submitted that Derrick `491 thereby teaches away from the presently claimed invention.

Caldwell `800 relates to a nasal cannula. This cannula, similar that of Derrick `491, is constructed with multiple individual pieces. According to a first embodiment, the nasal cannula is made up of a pair of nostril tubes 10 and 11 with a gas supply tube 13 passing therethrough, as best seen in Fig. 2. Communicating ports 14 allow gas to pass from the gas supply tube 13 to each of the nostril tubes 10 and 11. As the nostril tubes 10 and 11 are hollow and the one end not delivering gas is plugged with an end plug to prevent the escape of gas thereby.

According to second and third embodiments of Caldwell `800, the pair of nostril tubes 10 and 11, in the second embodiment, are a single unit which has the shape of a "U" with the gas supply tube again passing therethrough and, in the third embodiment, the gas supply tube is split and each end thereof is inserted into the nostril tubes 10 and 11, as best seen in Figs 4, 6 and 9. In short, each of the embodiments of Caldwell `800 relates to a cannula being made up of multiple individual pieces. As stated above the cannula, as manufactured in accordance with the method claims of the present application, comprises a molded component in which the fixed length hollow nasal prongs are formed as a single integral unit with the hollow body.

As the Examiner is aware, in order to properly support an obviousness rejection under 35 U.S.C. § 103(a), the cited references must teach or suggest all the claim limitations of the application. As pointed out above, the cannulas as taught and disclosed by both

Derrick `491 and Caldwell `800 comprise multiple pieces that are separately made and then combined with one another to form the resulting cannulas. Neither one of these references in any way teach or suggest integrally forming an inhalation fixed length prong and an exhalation fixed length prong with the hollow body as a single unitary construction for supplying all of the treating gas through the cannula, from the treating gas entrance to the treating gas exit, without allowing any of the treating gas to exhaust or exit through a side wall of the inhalation manifold, as presently recited.

In order to emphasize the above noted distinctions between the presently claimed invention and the applied art, each of the independent claims now recite the features of

[a] method of manufacturing a nasal cannula for insufflating a treating gas into a nose of a patient and measuring a carbon dioxide content in an exhalation gas of the patient, said method comprising the steps of: providing a hollow body with a treating gas entrance and an exhalation gas exit at opposed ends thereof, and separating the hollow body into a separate inhalation manifold and a separate exhalation manifold with the treating gas entrance communicating with the inhalation manifold and the exhalation gas exit communicating with the exhalation manifold. . . integrally forming a first fixed length hollow nasal prong with said inhalation manifold to define a treating gas insufflating passage extending between a treating gas entrance and a treating gas exit such that all of the treating gas supplied to the treating gas entrance is exhausted solely via the treating gas exit. . . integrally forming a second fixed length hollow nasal prong with the hollow body. . . forming at least one lateral opening in said second fixed length hollow nasal prong. . . and sizing the at least one lateral opening large enough to prevent sufficient suction from developing at the exhalation gas entrance to occlude the exhalation gas entrance, and small enough to prevent dilution of an exhaled gas sample by ambient air or excess insufflation gas.

Independent claim 10 recites internally partitioning the hollow body into a separate inhalation manifold and a separate exhalation manifold and while independent claim 12 further recites "integrally forming a second fixed length hollow nasal prong with the hollow body. . . such that all of the exhalation gas received by the exhalation gas entrance is exhausted solely via the exhalation gas exit. . .". Such features are believed to clearly and patentably distinguish the presently claimed invention from all of the art of record, including the applied art.

10/627,502

If any further amendment to this application is believed necessary to advance prosecution and place this case in allowable form, the Examiner is courteously solicited to contact the undersigned representative of the Applicant to discuss the same.

In view of the above amendments and remarks, it is respectfully submitted that all of the raised rejections should be withdrawn at this time. If the Examiner disagrees with the Applicant's view concerning the withdrawal of the outstanding rejections or applicability of the Derrick `491 and Caldwell `800 references, the Applicant respectfully requests the Examiner to indicate the specific passage or passages, or the drawing or drawings, which contain the necessary teaching, suggestion and/or disclosure required by case law. As such teaching, suggestion and/or disclosure is not present in the applied references, the raised rejection should be withdrawn at this time. Alternatively, if the Examiner is relying on his/her expertise in this field, the Applicant respectfully requests the Examiner to enter an affidavit substantiating the Examiner's position so that suitable contradictory evidence can be entered in this case by the Applicant.

In view of the foregoing, it is respectfully submitted that the raised rejections should be withdrawn and this application is now placed in a condition for allowance. Action to that end, in the form of an early Notice of Allowance, is courteously solicited by the Applicant at this time.

The Applicant respectfully requests that any outstanding objection(s) or requirement(s), as to the form of this application, be held in abeyance until allowable subject matter is indicated for this case.

In the event that there are any fee deficiencies or additional fees are payable, please charge the same or credit any overpayment to our Deposit Account (Account No. 04-0213).

Respectfully submitted,



Michael J. Bujold, Reg. No. 32,018

**Customer No. 020210**

Davis & Bujold, P.L.L.C.

Fourth Floor

500 North Commercial Street

Manchester NH 03101-1151

Telephone 603-624-9220

Facsimile 603-624-9229

E-mail: [patent@davisandbujold.com](mailto:patent@davisandbujold.com)



FIG. 1

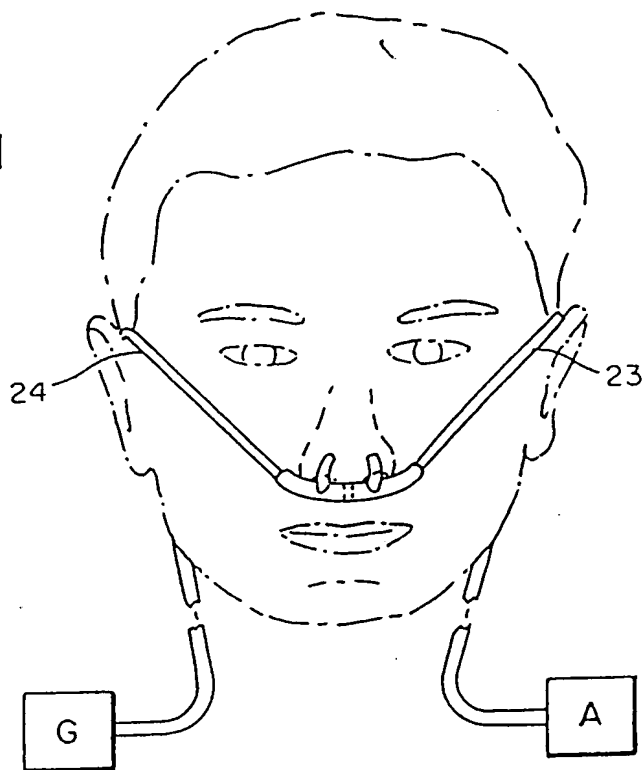


FIG. 3

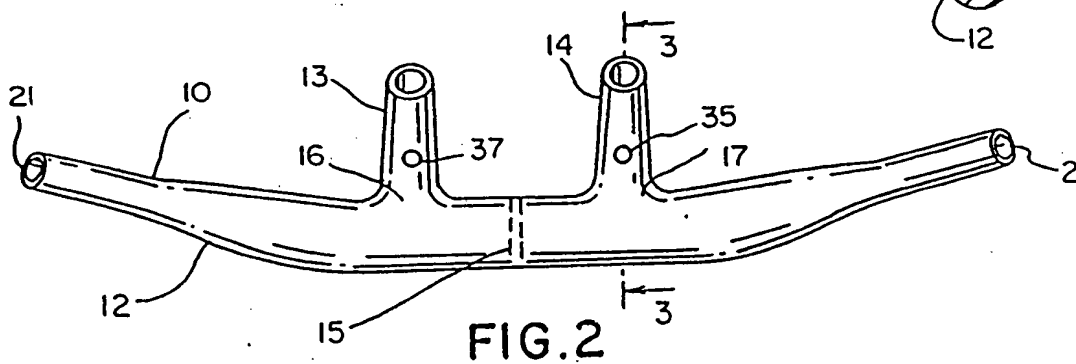
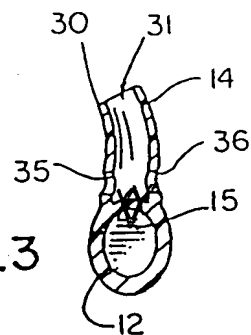


FIG. 2

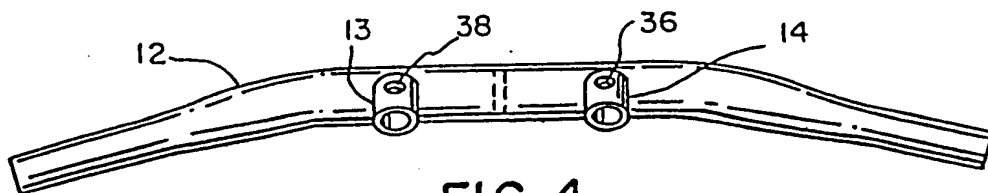


FIG. 4

BEST AVAILABLE COPY